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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,831	08/18/2000	C. Alexander Turner JR.	LEX-0035-USA	6428

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	10

DATE MAILED: 08/07/2002

Please find below and/or attached, an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/641,831	Applicant(s) TURNER ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. This action is in response to Paper No. 9, filed May 22, 2002. Applicants arguments presented in the response of Paper No. 9 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. It is noted that in claims 1, 3 and 5, the phrase "a nucleotide sequence described in SEQ ID NO: _" has been interpreted to mean "the nucleotide sequence", i.e., the full length sequence of the recited SEQ ID NO. This action is made final.

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to isolated nucleic acids comprising the sequence of SEQ ID NO: 1, 3, or 5 and nucleic acids encoding the amino acid sequence of SEQ ID NO: 2, 4 or 6. The specification refers to these nucleic acids as encoding NHPs (novel human proteins). The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well-established utility. The specification fails to provide objective evidence of any activity for the encoded polypeptides. Rather, the specification indicates that homology studies show that the putative proteins have identity with "a variety of putative secreted proteins, a tyrosine phosphatase, several human LIM proteins, as well as several cancer (colon, renal, and lung)

associated antigens" (page 12). It is further stated that the NHPs "share structural motifs typical of the human APXL protein- a protein that is similar to a Xenopus amiloride sensitive sodium channel" (page 2). While the specification states that the sequences of the polynucleotides have homology to other known proteins, the specification does not set forth a specific level of sequence identity shared, over the complete sequence, between the claimed polynucleotides and known polynucleotides encoding transporter proteins. Identity of a polynucleotide sequence to other known polynucleotides does not by itself establish that a polynucleotide will encode for a product having the same activity as the known polynucleotides because a change at even a single amino acid position may affect a proteins function and a change at a single nucleotide position may affect the ability of a polynucleotide to encode for a polypeptide. Furthermore, no information is provided regarding the conservation of any particular domains which are required for transporter function or which are characteristic of specific types of transporter proteins. Accordingly, there is no evidence of record to suggest that the claimed polynucleotides do in fact encode for polypeptides a particular activity. In addition, the specification does not distinguish between which polynucleotides have identity to APXL, which have identity to "secreted proteins", which have identity to a tyrosine phosphatase, which have identity to a LIM protein, and which have identity to a cancer antigen. Moreover, these types of proteins fall into very general classes of proteins and are not considered to constitute a specific activity for utility purposes. The specification (for example, 12) suggests that the claimed polynucleotides could be used for therapeutic purposes or for diagnosis of disease. However, no specific diseases have

been identified which are correlated with expression of the claimed polynucleotides. Clearly, further research would be required to identify a disease for which the encoded protein is involved and for which treatment with the encoded proteins would be effective or for which detection of expression of SEQ ID NO: 1, 3 or 5 would be informative. As stated in Brunner v. Manson, 383 U.S. 519 535-536, 148 USPO 689, 696 (1966) " a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". The specification (see, for example, pages 30, 35 and 38) further asserts that the polynucleotides of SEQ ID NO: 1, 3 and 5 and the proteins of SEQ ID NO: 2, 4 and 6 can be used in drug screening methods. However, because the specification has not established that the proteins of SEQ ID NO: 2, 4 and 6 have a functional activity, the general concept of using any compound for the purposes of screening for agents which bind this compound is not considered to be a specific utility. While nucleic acids comprising SEQ ID NO: 1, 3 and 5 could be expressed to obtain protein for use in research aimed at determining or characterizing the polypeptides function, such use is general, rather than specific and substantial. Support for an asserted utility that is specific and substantial would require, for example, a showing of a particular function for an encoded polypeptide. Merely identifying and studying the properties of a polypeptide or the diseases in which a polypeptide may be involved does not constitute a "real world" context of use. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

3. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, or credible asserted utility or well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 9, Applicants traverse the above rejections. Applicants state that "the novel protein of the present invention contains an amino-terminus PDZ actin binding domain found in, for example, APXL and shroom related proteins...The carboxy terminus of the protein has ATP binding and ATPase (V type) motif domains. The novel protein of the present invention is part of a macromolecular complex of proteins forming a channel complex, its role is most likely to anchor the complex to the membrane." Based on these "facts", Applicants conclude that "the assertions regarding the protein of the present invention are credible". However, the response and the originally filed specification do not clarify whether each of the claimed nucleic acids encodes for the above described protein or whether only one of the nucleic acids encode for this protein. The specification describes nucleic acids encoding proteins having very distinct functions, including proteins having APXL activity, proteins which have identity to "secreted proteins", proteins which have identity to a tyrosine phosphatase, proteins which have identity to a LIM protein, and proteins which have identity to a cancer antigen. Since the specification does not clearly set forth the function of the protein encoded by each nucleic acid, the specification has not described a specific utility for each nucleic acid and has not adequately

taught one of skill in the art how to use the claimed nucleic acids. Further, Applicants response notes that one of the nucleic acids encodes for a protein having an amino-terminus characteristic of APXL and shroom related proteins. There is no evidence of record to indicate that the presence of this amino-terminus alone would indicate to one of skill in the art that the presently claimed nucleic acid encodes for a APXL protein and that the encoded protein would have a specific activity and well known use. Applicants response also asserts that one of the claimed nucleic acids encodes for a protein having an amino acid terminus shared with "shroom related proteins". However, the specification as originally filed does not teach that the claimed nucleic acids encode for "shroom related proteins". The specification as originally filed must teach the use of the claimed nucleic acids. Applicants statement that the claimed nucleic acid may encode for a protein whose role is "most likely" to anchor the complex to the membrane clearly emphasizes the uncertainty in determining the function and activity of the encoded protein. Further, the specification as originally filed does not appear to state that the claimed nucleic acids are useful for encoding proteins that have the functional activity of anchoring a macromolecular complex to a membrane. Again, the utility of the claimed nucleic acid must be set forth in the originally filed specification.

Applicants assert that the claimed nucleic acids have a substantial utility because they can be used in gene chips as a "specific markers of the human genome and such specific markers are targets for the discovery of drugs that are associated with human disease". It is stated that "Knowing that a given gene is not expressed in a medically relevant tissue provides an

informative finding of great value to the industry by allowing for the more efficient deployment of expensive drug discovery resources." These arguments are not persuasive because the disclosed nucleic acids have not been shown to be associated with any particular disease. It is agreed that the finding that a gene is not expressed in a specific tissue is a valuable research result. However, there is no evidence in the specification that any of the claimed nucleic acids are not expressed in a single specific tissue and are associated with the occurrence of a specific disease. It has not been established that the claimed nucleic acids could be used for the diagnosis of a specific disease or for the development of drugs to treat a particular disease. Clearly further research would be required to identify a disease, if one exists, in which expression of the disclosed nucleic acids are associated. Furthermore, the use of the claimed nucleic acids as markers of the human genome and in assisting in the analysis of the human genome is not considered to be a specific and substantial utility because this is a general utility associated with all human nucleic acids. While each of the research projects set forth in Applicants response could provide valuable information regarding the function of the proteins encoded by the claimed nucleic acids, the use of the claimed nucleic acids as a research tool does not constitute a specific and substantial utility.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER

August 1, 2002